

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex V

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
PRISMAN GmbH

Otto-Hahn-Ring 6-18, 64653 Lorsch, Germany

Certified location:

Otto-Hahn-Ring 6-18, 64653 Lorsch, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50681-Z5-00, the decision dated 2019-05-28 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-05-30 to 2024-05-26

Registration No.: 50681-17-05



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-05-28
Notified Body ID-number: 0124



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-295.10.02
www.zlg.de

Annex to the EC Certificate No. 50681-17-05

Valid from 2019-05-30 to 2024-05-26

Revision status of the annex: 0 dated 2019-05-28

Devices/device categories included in the certificate:

Class II a:

MD0108

Suction System Disinfection

- Suction System Disinfection conc., SS 400 conc.

Surface Disinfection

- Surface Disinfection BASIS conc., SD 200 conc.
- Surface Disinfection conc., SD 300 conc.
- Surface Disinfection PROTECT conc., SD 420 conc.
- Surface Disinfection PREMIUM conc., SD 240 conc.
- Surface Disinfection PREMIUM POWDER conc., SDP 800 conc.
- Surface Disinfection RAPID FOAM PLUS, RFD 440 including Disinfection Wipes
- Surface Disinfection RAPID FOAM HIGH, RFD 740 including Disinfection Wipes

Impression Disinfection

- Impression Disinfection PLUS, IM 400
- Impression Disinfection, IM 200
- Impression Disinfection, IM 250

Spittoon Disinfection

- Spittoon Disinfection SPITTOON, SP 400
- Mundspülbeckendesinfektion NANO, SPN 700

Rapid Surface Disinfection

- Spittoon Disinfection, RSD 400 including Disinfection Wipes

MD0402

Etching Gel

- Etching Gel

Primer

- Silanization Liquid SILANO



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